

Central IRB and E-Consent



"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

Objectives

- Why a central IRB?
- What a CIRB is and is not.
- How it works.
- The e-consent platform

Why a central IRB?

NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site...
NOT-OD-16-094: Final N X

Secure | <https://grants.nih...>

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Notice Number: NOT-OD-16-094

Key Dates

Release Date: June 21, 2016
Effective Date: New Date - January 25, 2018 as per issuance of [NOT-OD-17-076](#)

Related Announcements

- [NOT-OD-18-004](#)
- [NOT-OD-18-003](#)
- [NOT-OD-17-076](#)
- [NOT-OD-17-027](#)
- [NOT-OD-16-109](#)

Issued by

National Institutes of Health (NIH)

Purpose

The National Institutes of Health (NIH) is issuing this policy on the use of a single Institutional Review Board (IRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the

Why a central IRB?

- Empowerment
- Equity
- Efficiency



What a CIRB is and is not

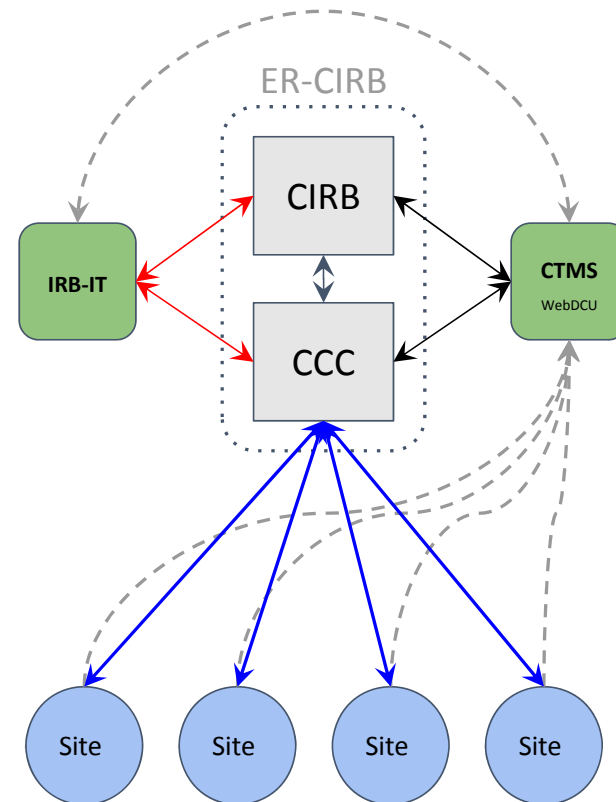
- It IS a replacement for your local IRB panel
 - Protocol review, consent review, site applications, AE's, ORIO's, SCR's
- It IS NOT a replacement for everything your local IRB office does
 - Contracts, staff training, certification, billing, COI, radiation comm, etc.

How it works

- Sponsor
- Reliance agreements
- Local processes
- Ceding documents
- Site applications
- Approvals
- AE and ORIO reporting
- SCR

How it ~~works~~ will work

- Communication
- Data flow
- Avoid triplicative data entry
- Avoid download/upload

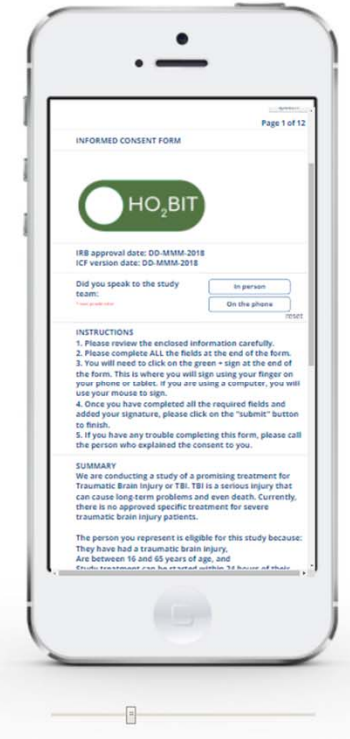
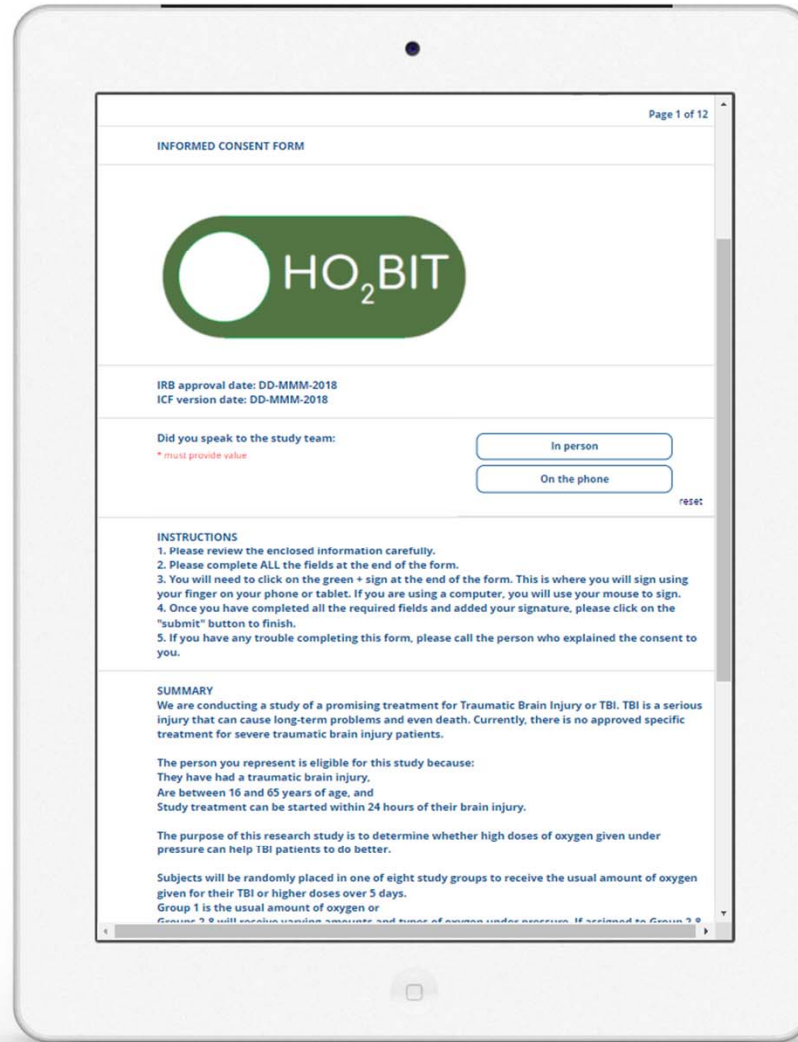


E-consent document

- Consent remains a human process
- Adjustable text size
- Error reduction
- Compliant remote consent documentation
- Completes the web based study binder
- Facilitate remote monitoring

[Link to simulator](#)

- RedCap
- Compliant
- Web based



Questions?



February 2018
DSMB Meeting

